510(k) Summary for exsalt™ SD7 Wound Dressing

MAY 2 0 2011

1. Trade (Proprietary) Name

exsalt™ SD7 Wound Dressing

2. Common Name

Wound or Burn Dressing

3. Contact Information

Contact: Mr. Rod Precht
President and Founder

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Date of 510(k) Summary Preparation: October 1, 2010

4. Device Classification & Panel

A final classification for wound/burn dressings has not been implemented; Class II has been proposed by the General & Plastic Surgery Devices Panel.

5. Predicate Device(s)

exsalt™ SD7 Wound Dressing (K083870)

6. Device Description

Exciton Technologies Inc. has developed the exsalt™ technology, a proprietary chemical process, which deposits oxidized silver species onto a non-woven needled polyester coated with gray Delnet® HDPE mesh layers on both sides (STRATEX®). Silver in the exsalt™ SD7 Wound Dressing inhibits microbial growth in the dressing. The concentration of the silver and oxidized silver species on the dressing is 0.4 mg/cm^2 (2.5% w/w). The exsalt™ SD7 Wound

Dressing has been shown to be effective *in vitro* against *Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa, and Enterococcus faecalis* when they are in direct contact with the dressing. In addition, *in vitro* data have demonstrated that exsalt™ SD7 Wound Dressing maintains its antibacterial activity for up to 7 days against *Pseudomonas aeruginosa* and *Staphylococcus aureus.*

7. Intended Use

exsalt™ SD7 Wound Dressing is indicated for the management of partial and full thickness wounds, including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, grafts and donor sites, or other acute or chronic wounds. The dressing may be used over debrided and grafted wounds.

8. Summary of Substantial Equivalence

The labeled indications and directions for use of the exsalt™ SD7 Wound Dressing are equivalent to those of the predicate device, exsalt™ SD7 Wound Dressing (K083870), with the additional claim that it maintains its antibacterial activity for up to 7 days as shown *in vitro* against *Pseudomonas aeruginosa* and *Staphylococcus aureus*. The design, materials, and manufacturing methods are similar to those of the predicate device, exsalt™ SD7 Wound Dressing (K083870), and therefore do not raise any new issues concerning safety or effectiveness.

a) Summary of Technological Characteristics

The exsalt™ SD7 Wound Dressing consists of 2 outer layers of HDPE with an inner layer of absorbent polyester which are all silver-coated. The skin-contacting materials in both the exsalt™ SD7 Wound Dressing and the predicate are the same.

For the predicate device (K083870), silver was deposited on the exsalt™ SD7 Wound Dressing using an aqueous chemistry (emersion) approach. This application process has been changed to an aqueous chemistry (direct coating) of the silver onto the substrate. This method of application of the silver to the dressing does not affect the efficacy or safety of the device as the final product specifications remain unchanged. exsalt™ SD7 Wound Dressing is sterilized by gamma irradiation.

In summary, the change in the exsalt™ SD7 Wound Dressing manufacturing process does not raise any concerns related to safety or effectiveness as compared to the predicate device (K083870).

b) Summary of Performance Data

The following performance tests were conducted on the exsalt™ SD7 Wound Dressing:

- Absorptive Capacity
- Moisture Content
- Drop Penetration
- Adhesion
- Abrasion
- Silver Content
- Anti-microbial (Bacterial) Effectiveness
- Bactericidal Effectiveness
- Biocompatibility
- Biological Reactivity

Absorptive capacity, moisture content, adhesion, and abrasion characteristics are the same as the predicate.

The exsalt™ SD7 Wound Dressing showed no new safety concerns relative to biocompatibility. The predicate was shown to be non-toxic, non-irritant, and did not elicit a sensitization response.

The exsalt™ SD7 Wound Dressing (K083870) has been shown to be effective *in vitro* against *Staphylococcus aureus, Escherichia coli, Pseudomonas aeruginosa and Enterococcus faecalis.* In addition, *in vitro* data have demonstrated that exsalt™ SD7 Wound Dressing maintains its antibacterial activity for up to 7 days against *Pseudomonas aeruginosa* and *Staphylococcus aureus.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

MAY 2 0 2011

Exciton Technologies, Inc.
% Mr. Rod Precht
10230 Jasper Avenue, Suite 4232
Edmonton, Alberta T5J 4P6
Canada

Re: K103067
Trade/Device Name: exsalt™ SD7 Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 07, 2011
Received: April 11, 2011

Dear Mr. Precht,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

exsalt™ SD7 Wound Dressing Indications for Use

510(k) Number (if known): K103067

Device Name: exsalt™ SD7 Wound Dressing

Indications For Use:

The exsalt™ SD7 Wound Dressing is indicated for the management of partial and full thickness wounds, including decubitus ulcers, venous stasis ulcers, diabetic ulcers, first and second degree burns, grafts and donor sites, or other acute or chronic wounds. The dressing may be used over debrided and grafted wounds.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103067